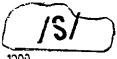
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-017

21-018

MICROBIOLOGY REVIEW(S)



JAN 29 1999

REVIEW TO HFD-510 OFFICE OF NEW DRUG CHEMISTRY MICROBIOLOGY STAFF MICROBIOLOGIST REVIEW OF A NDA January 21, 1999

A. NDA 21-017

PRODUCT	NAME:	Humalog®	Mix25TM

25% Insulin Lispro Injection and 75% Insulin Lispro

Protamine Suspension (rDNA origin)

APPLICANT: Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46285

DOSAGE FORM: Injectable, 100 Units/mL for Subcutaneous administration METHOD-OF STERILIZATION: PHARMACOLOGICAL CATEGORY: Treatment of hyperglycemia

В. INITIAL APPLICATION DATE:

December 21, 1998

ASSIGNED FOR REVIEW:

January 4, 1999

C. REMARKS: This NDA which provides for Humalog®Mix25™ in 10 mL vials and in 3.0 mL cartridges is the same as NDA 21-018 which provides for Humalog®Mix50™, except for items 2 (Labeling), 3 (Application Summary) and 4 (Chemistry Section). Product quality microbiology CMC information is included under item 7 and is the same in both NDAs.

D. CONCLUSIONS: The NDA 21-017 for Humalog®Mix25™ is approvable pending resolution of product quality microbiology issues.

Patricia F. Hughes, Ph. D. Review Microbiologist

cc.: Original NDA 21-017 HFD-160 /Consult File

HFD-805/PFHughes HFD-510/JRhee HFD-510/Division File

Drafted by PFHughes/January 21, 1999 R/D Initialed by PHCooney

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REVIEW TO HFD-510 OFFICE OF NEW DRUG CHEMISTRY MICROBIOLOGY STAFF MICROBIOLOGIST REVIEW OF A NDA January 21, 1999

A. NDA 21-018

PRODUCT NAME: Humalog® Mix50™

50% Insulin Lispro Injection and 50% Insulin Lispro

Protamine Suspension (rDNA origin)

APPLICANT: Eli Lilly and Company

Lilly Corporate Center Indianapolis, IN 46285

DOSAGE FORM: Injectable, 100 Units/mL for Subcutaneous administration

METHOD OF STERILIZATION:

PHARMACOLOGICAL CATEGORY:

Treatment of hyperglycemia

B. INITIAL APPLICATION DATE:

ASSIGNED FOR REVIEW:

December 21, 1998 January 4, 1999

C. REMARKS: This NDA which provides for Humalog Mix50TM in 10 mL vials and in 3.0 mL cartridges is the same as NDA 21-017 which provides for Humalog®Mix25™, except for items 2 (Labeling), 3 (Application Summary) and 4 (Chemistry Section). Product quality microbiology CMC information is included under item 7 and is the same in both NDAs.

D. CONCLUSIONS: The NDA 21-018 for Humalog®Mix50™ is approvable pending resolution of product quality microbiology issues.

Patricia F. Hughes, Ph. D. Review Microbiologist

1/20/99

cc.: Original NDA 21-018

HFD-160 /Consult File

HFD-805/PFHughes

HFD-510/JRhee

HFD-510/Division File

Drafted by PFHughes/January 21, 1999

R/D Initialed by PHCooney



REVIEW TO HFD-510 OFFICE OF NEW DRUG CHEMISTRY MICROBIOLOGY STAFF MICROBIOLOGIST REVIEW OF AN AMENDMENT 9 April 1999

A. NDA 21-017

PRODUCT NAME: Humalog® Mix25™

25% Insulin Lispro Injection and 75% Insulin Lispro

Protamine Suspension (rDNA origin)

APPLICANT: Eli Lilly and Company

Lilly Corporate Center Indianapolis, IN 46285

DOSAGE FORM: Injectable, 100 Units/mL for Subcutaneous administration

METHOD OF STERILIZATION:

PHARMACOLOGICAL CATEGORY: Treatment of hyperglycemia

B. INITIAL APPLICATION DATE:

21-December 1998

DATE OF AMENDMENT # 1:

17 February 1999

ASSIGNED FOR REVIEW:

1 March 1999

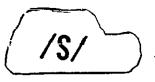
C. REMARKS: The amendment dated February 17, 1999 contains responses to microbiology deficiencies found in the original application.

D. CONCLUSIONS: The NDA 21-017 for Humalog®Mix25™ is recommended for approval from the standpoint of product quality microbiology.

Patricia F. Hughes, Ph. D. Review Microbiologist

cc.: Original NDA 21-017 HFD-160 /Consult File HFD-805/PFHughes HFD-510/JRhee HFD-510/Division File Drafted by PFHughes/9 April 1999 P/D Initialed by PHCooney





REVIEW TO HFD-510 OFFICE OF NEW DRUG CHEMISTRY MICROBIOLOGY STAFF MICROBIOLOGIST REVIEW OF AN AMENDMENT 9 April 1999

APR | 2 1993

A. NDA 21-018

PRODUCT NAME: Humalog® Mix50™

50% Insulin Lispro Injection and 50% Insulin Lispro

Protamine Suspension (rDNA origin)

APPLICANT: Eli Lilly and Company Lilly Corporate Center

Indianapolis, IN 46285

DOSAGE FORM: Injectable, 100 Units/mL for Subcutaneous administration

METHOD OF STERILIZATION:

PHARMACOLOGICAL CATEGORY: Treat

Treatment of hyperglycemia

B. INITIAL APPLICATION DATE:

21-December 1998

DATE OF AMENDMENT # 1:

17 February 1999

ASSIGNED FOR REVIEW:

1 March 1999

C. REMARKS: The amendment dated February 17, 1999 contains responses to microbiology deficiencies found in the original application.

D. CONCLUSIONS: The NDA 21-018 for Humalog®Mix50™ is recommended for

approval from the standpoint of product quality microbiology.

Patricia F. Hughes, Ph. D.

Review Microbiologist

cc.: Original NDA 21-018

HFD-160 /Consult File HFD-805/PFHughes HFD-510/JRhes-HFD-510/Division File Drafted by PFHughes/9 April 1999

N/D Initialed by PHCooney

APPEARS THIS WAY ON ORIGINAL